UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PHARMASTEM THERAPEUTICS, INC., a Delaware corporation,

Plaintiff,

v.

VIACELL, INC., a Delaware corporation, OBSTETRICAL AND GYNECOLOGICAL ASSOCIATES, P.A., FEMPARTNERS, INC., a Delaware corporation and CARITAS ST. ELIZABETH'S MEDICAL CENTER OF BOSTON, INC., a Massachusetts Nonprofit Corporation,

Defendants.

Civil Action No. 04-CV-11673 RWZ

EXHIBIT 1

TO

DECLARATION OF ATTORNEY EDWARD W. LITTLE, JR.

EXHIBIT 484

ISSUES -

1) Competition

New Industry

Autologous and allogeneic stem/progenitor cell banking is a new industry. Two key competitors exist offering umbilical cord blood stem cell banking. They are: Biocyte Corporation of Stamford, Connecticut and CryoCell International, Inc. of Baldwin, NY.

Biocyte: Biocyte, established in 1985, specifically for banking Cord Blood Stem Cells. They spent nine years in development and started banking product commercially in November, 1993. Financing by Rodman Rockefeller and Radnor Venture Partners and others has and continues to support their efforts for the past nine years. Biocyte launched its offering at Magee Women's Hospital in Pittsburgh. They have contracted the Central Blood Bank of Pittsburgh as their central processing facility. They are offering strictly autologous cord blood banking for a period of eighteen years. The company most likely will launch nationally in 1994.

Biocyte has two patents on cord blood. They have patented the cryopreservation and therapeutic use of hematopoietic stem and progenitor cells derived from umbilical cord and placental blood. These patents are currently in reexamination by the U.S. Patent office (see Patents below). The patents they hold are broad and in question due to prior art in the field. They have been in reexamination since October, 1993. The patents are a known and acknowledged risks. The verdict will play a role in the outcome and success of this business opportunity.

We view Biocyte as our strongest competitor. The founding scientists' are core researchers in this field and have published many related articles. Biocyte's time, energies, and financial resources have been spent doing much education and development in this field. They are the trailblazers. Cross country skiing behind the trail blazer conserves energy and resources. Viacord's low overhead and low burn rate are key advantages to the business opportunity at this early stage. Another advantage of Viacord's is its alliances with local and regional stem/cell processing laboratories involving them as a partner in this new market opportunity.

Cryocell: Cryocell International, Inc. was established in 1989 in Baldwin, NY. Cryocell has patented a freezer technology for vial storage of cord blood or other specimens. Their plan is to install freezers in hospitals and charge a yearly service fee per vial stored. They supposedly will launch in 1994 at New England Medical Center in Boston offering freezing for $50 per 5 ml vial stored. According to transplanters who have successfully transplanted pediatric cases, approximately one hundred mls of cord blood, anticoagulant, and cryoprotectant is frozen for transplant. Separation to a simple 5 ml volume is not established in today's science. Cryocell is a public company (CCEL). The company has established various creative stock related relationships and agreements with InstaCool and others. Cryocell challenged Biocyte's patents putting the patents in reexamination. We view Cryocell as a second tier player with the weaknesses being in the dependence of the health care giver to provide, market, and administer the inventory. However, if their freezer system develops as they indicated, they would provide the marketplace with a much needed added value labeling and inventory tracking system built-in.

2) Patents

Industry Patents

A competitor to Viacord, Biocyte Corporation holds U. S. Patent # 5004681 and # 5192553 patenting the cryopreservation of hematopoetic stem and progenitor cells of umbilical cord and placental blood. These patents, though approved March, 1991, and March, 1993, respectively, currently are under reexamination by the U. S. Patent office. The reexamination is a result of prior art found and disclosed to the patent office by Cryo-Cell International, of Baldwin, NY.

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Viacord, Inc. is well aware of the risks these patents present. The outcome of the reexamination will be a determining factor effecting this business opportunity. We have sought the opinions of two patent law firms; both are of the opinion that the patents are invalid. However, at this time we look to the patent office to establish the same opinion and negate the patents.

Prior to the reexamination, Viacord proposed a licensing agreement with Biocyte and was declined. The company indicated they had no intention to license their technology.

3) FDA Regulation

The field of Bone Marrow Transplantation has not been regulated. According to the October, 1993, Federal Register, the FDA will not regulate the field at this time, but intends to in the future. Nearer term the FDA will regulate somatic cell and gene therapy. Cord blood and peripheral blood progenitor cell banking will fall under somatic cell therapy when separation techniques to the stem or progenitor cell levels are utilized and when cell expansion is implemented. Various separation techniques are being employed today that may or may not fall under this new regulation.

Viacord plans to proactively put in place standards in line and ahead of this regulation. Important to our customers, the transplant community, and our strategy is to offer highest level of quality and security. To address this regulation, we have four concurrent approaches:

(1) Our VP of Operations brings direct manufacturing experience in the pharmaceutical area of compliance. Biologics (blood banking) is moving in the direction of pharmaceuticals. His knowledge of current good manufacturing practices (cGMP) will help us foresee the issues and put in place proactive controls.

(2) We will contract (partner) with stem/progenitor cell processing labs that offer the highest quality processing in the field, have a strong history of FDA compliance, and are well established to address implement FDA regulation.

(3) We have and will continue to bring in outside regulatory expertise to advise us on systems and procedures and perform intermitant audits to monitor our progress.

(4) We will work with the FDA on a continual basis to work with them and help influence the model for regulation in this field.

(5) We will keep in close communication with our contract labs and the FDA so that there are no surprises for either the FDA, the lab, or Viacord.

Insurance/Customer Assurance

To address the concern of providing parents with assurance that they can continue to bank the product if Viacord or the contract lab ceases operations, Viacord plans to offer a "product assurance program". Here, Viacord would arrange a type of reinsurance agreement with well established partners from the from tangential industries such as health plan providers, a major insurer, and a major blood banking industry supplier. This group would offer continued banking services for an agreed to yearly maintenance fee.

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